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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/955,373	MOURITSEN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85-101* is/are pending in the application.

4a) Of the above claim(s) *88-100* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-87,101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 85-87,101 are under consideration.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 85-87,101 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed invention.

The instant claims encompass a method that uses a mutant analogue peptide wherein the analogue peptide has a substituted foreign immunodominant T cell epitope with the functional properties recited in the claim. Whilst the specification discloses a particular example of a particular molecule with a particular substitution which apparently has the properties recite in the claims, the claims encompass a vast collection of mutant molecules with the properties recited in the claims that are not disclosed in the specification. It is unpredictable as to what particular substitutions can be made to any particular molecule and result in a mutant analogue molecule with the functional attributes recited in the claims.

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the facts are similar to those disclosed in University of California v. Eli Lilly and Co. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, the instant claims encompass a method that uses a mutant analogue peptide wherein the analogue peptide has a substituted foreign immunodominant T cell epitope with the functional properties recited in the claim. Whilst

the specification discloses a particular example of a particular molecule with a particular substitution which apparently has the properties recite in the claims, the claims encompass a vast collection of mutant molecules with the properties recited in the claims that are not disclosed in the specification. It is unpredictable as to what particular substitutions can be made to any particular molecule and result in a mutant analogue molecule with the functional attributes recited in the claims. In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the facts are similar to those disclosed in University of California v. Eli Lilly and Co. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Regarding applicants comments about screening methods,

the MPEP section 2163, II.A.3.(a) states:

An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95.

The various screening methods to which applicant refers in the specification are "*merely a wish or plan for obtaining the chemical invention claimed".* An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95. There is no disclosure in the specification as to the identity of particular of particular amino acid sequences that can be used in the claimed invention (other than the one specific example disclosed in the specification). Applicant is also referred to Example 10, claim 3 of the Written description guidelines (available on the PTO website). It is also noted that said example refers to an example wherein 95% of the amino acids are the same wherein the claimed invention is not so limited (it encompasses mutants with less than 95% similarity). Applicants own comments indicate that the identity of molecules used in the claimed method is unpredictable and needs to be established after the fact using screening methods.

4. The rejection of claims 85-87,101 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office action are withdrawn in view of the amended claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 85-87,101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 85 is indefinite in the recitation of "the tertiary structure of the pathogenic self-protein is essentially preserved" because it is unclear what this means or encompasses. It is unclear what changes to the tertiary structure would or would not be encompassed by the aforementioned term. For example, it is unclear if this term

encompasses changes at the physical/chemical level (eg. crystal structure) or simply functional changes (eg. still immunogenic antigen as evidenced by antibody binding by antibodies specific for unmodified antigen). If the term is interpreted as encompassing changes at the physical/chemical level, it is unclear as to what deviations from the normal crystal structure would or would not be encompassed by the term "essentially preserve the overall tertiary structure". It is unclear as to what changes to the tertiary structure would or would not be encompassed by the aforementioned term. For example, it is unclear if this term encompasses changes at the physical/chemical level (eg. crystal structured) or simply functional changes (eg. still immunogenic antigen as evidenced by antibody binding by antibodies specific for unmodified antigen). If the term is interpreted as encompassing changes at the physical/chemical level, it is unclear as to what deviations from the normal crystal structure would or would not be encompassed by the term "essentially preserve the overall tertiary structure".

The MPEP section 2173.02 states:

Clarity and Precision

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement. The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;
(B) The teachings of the prior art; and
(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.
If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. In re Wiggins, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

Claim 86 is indefinite in the recitation of "preserve N-terminal and C-terminal flanking regions" because it is unclear what this term means or encompasses.
There is no definition of said term in the specification and said term has no art recognized meaning. It is unclear as to what changes to a molecule would be encompassed by the term under consideration.

7. Claims 85-87,101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants arguments have been considered and deemed not persuasive.

Claim 85 is indefinite in the recitation of "pathogenic self-protein " because it is unclear what this means or encompasses. Said term is not defined in the specification and has no art recognized definition. It is unclear if said term applies to mutant versions of normal proteins or normal proteins or normal proteins expressed at abnormal levels or normal proteins that contain epitopes that cross react with exogenous pathogenic proteins or combinations of the aforementioned. Regarding applicants comments about what that said term means, the cited passage of the specification does not clarify the meaning of the aforementioned terms. Furthermore, the term "pathogenic self-protein" is not even used in said passage of the specification.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 85 and 86 stand rejected under 35 U.S.C. 102(b) as being anticipated by Russell-Jones et al. (WO 92/05192) as evidenced by Dean et al. (US Patent 5,716,596). Applicants arguments have been considered and deemed not persuasive.

Russell-Jones et al. teach T cell epitopes derived from Trat protein (see Abstract). Russell-Jones et al. teach Trat T cell epitopes are inserted into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26 and Abstract). Russell-Jones et al. teach that the Trat peptide is inserted such that the protein still functions as an immunogen. The Trat peptide has been inserted into the immunogen in such a manner as to essentially preserve the overall tertiary structure, because the ability of the immunogen to function as an immunogen is maintained (see page 8, first complete paragraph). Russell-Jones et al. teach that the Trat modified immunogen can be used as a vaccine in a composition containing an adjuvant such as saponin (see page 8 and 13). Russell-Jones et al. teach that using recombinant DNA technology that Trat peptide can be inserted into the immunogen via substituting Trat peptide for a peptide contained in said molecule (see page 32 and page 31, first incomplete paragraph). Said insertion would preserve flanking regions on both sides of the Trat T cell epitope. Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Russell-Jones et al. teach that such vaccines can be used in animals and humans. Whilst the term “pathogenic self protein” is indefinite, for the purposes of this rejection it will be interpreted as encompassing a normal protein related to a disease. Somatostatin is inherently a “pathogenic self protein” in view of its art recognized role in a variety of diseases (see Dean et al., column 2, first paragraph and column 6, third paragraph from bottom).

Regarding applicants comments about “self proteins”, Russell-Jones et al. teaches that the claimed invention can be used as a vaccine in humans (see page 33) and can be

used to raise antibody responses against such proteins as luteinizing hormone, somatostatin, inhibin, FSH (eg. ***self proteins***). Whilst the term "pathogenic self protein" is indefinite, for the purposes of this rejection it will be interpreted as encompassing a normal protein related to a disease or undesired function. Somatostatin is inherently a "pathogenic self protein" in view of its art recognized role in a variety of diseases (see Dean et al., column 2, first paragraph and column 6, third paragraph from bottom). In fact, all of the proteins referred to in Russell-Jones et al. must be involved in a unwanted function or else there would be no reason to induce antibodies against said molecules. Regarding applicants comments about "suppressor regions", that particular example of the Russell-Jones et al. reference is not referred to in the instant rejection. Russell-Jones et al. teach that, "The at least one "immunogen" which forms part of the complex *is any molecule which it is desirable to use to raise an immune response*.". Regarding applicants comments about somatostatin, there is no evidence of record that the invention of Russell-Jones et al. lacks enablement regarding this particular embodiment. The prior art is considered enabled in the absence of evidence to the contrary. Furthermore, Russell-Jones et al. teach that one such immunogen could include luteinizing hormone or FSH or inhibin (see page 9).

Regarding applicants comments, Russell-Jones et al. teach that their invention encompasses vaccines for use in animals and humans (see page 33). Russell-Jones et al. teach that one such immunogen could include luteinizing hormone or somatostatin or FSH or inhibin (aka ***self proteins*** see page 9). Said proteins could only be of two different origins (human or nonhuman). Thus, based on the disclosure of Russell-Jones et al., one of ordinary skill in the art would at once envisage use of human self-protein as a vaccine as per page 33 of Russell-Jones. Russell-Jones et al. teach Trat T cell epitopes are inserted into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26, page 31, lines 4-8, claim 14 and Abstract). Russell-Jones et al. teach that the Trat peptide is inserted such that the protein still functions as an immunogen. Russell-Jones et al. teach that the Trat modified immunogen can be used as a vaccine in a composition containing an adjuvant such as saponin (see page 8 and 13). Russell-

Jones et al. teach that using recombinant DNA technology that Trat peptide can be inserted into the immunogen via substituting Trat peptide for a peptide contained in said molecule (see page 31, first incomplete paragraph and claim 14 wherein the nucleic acid of claim 14 is used to recombinantly produce said protein). Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Russell-Jones et al. teach that such vaccines can be used in animals and humans. Regarding applicants comments and the Travers and Zinkernagel declarations, said declarations have been addressed in the previous Office actions. The Zinkernagel declaration deals with suppressor regions and comments about Travers. As per above, "suppressor regions" are not part of the prior art that is cited in the instant rejection. Thus, the Zinkernagel declaration is irrelevant to the issues under consideration. Most of the Travers declaration deals with "suppressor regions" which are not part of the prior art that is cited in the instant rejection. Regarding other comments in the Travers declaration, Russell-Jones et al. teach that their invention encompasses vaccines for use in animals and humans (see page 33). Russell-Jones et al. teach that one such immunogen could include luteinizing hormone or somatostatin or FSH or inhibin (aka ***self proteins*** see page 9). Regarding applicants comments about paragraph 10 of the Travers declaration, Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Regarding applicants comments about "suppressor regions", that particular example of the Russell-Jones et al. reference is not referred to in the instant rejection.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 85-87 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Russell-Jones et al. (WO 92/05192) in view of Dean et al. (US Patent 5,716,596).

Russell-Jones et al. teach T cell epitopes derived from Trat protein (see Abstract). Russell-Jones et al. teach Trat T cell epitopes are inserted into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26 and Abstract). Russell-Jones et al. teach that the Trat peptide is inserted such that the protein still functions as an immunogen. The Trat peptide has been inserted into the immunogen in such a manner as to essentially preserve the overall tertiary structure, because the ability of the immunogen to function as an immunogen is maintained (see page 8, first complete paragraph). Russell-Jones et al. teach that the Trat modified immunogen can be used as a vaccine in a composition containing an adjuvant such as saponin (see page 8 and 13). Russell-Jones et al. teach that using recombinant DNA technology that Trat peptide can be inserted into the immunogen via substituting Trat peptide for a peptide contained in said molecule (see page 32 and page 31, first incomplete paragraph). Said insertion would preserve flanking regions on both sides of the Trat T cell epitope. Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Russell-Jones et al. teach that such vaccines can be used in animals and humans. Whilst the term “pathogenic self protein” is indefinite, for the purposes of this rejection it will be interpreted as encompassing a normal protein related to a disease. Somatostatin is a “pathogenic self protein” in view of its art

recognized role in a variety of diseases (see Dean et al., column 2, first paragraph and column 6, third paragraph from bottom). Russell-Jones et al. do not teach use of immunodominant foreign T cell epitopes derived from diphtheria toxoid. Russell-Jones teach that immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art (see page 4, first paragraph). Russell-Jones et al. teach that diphtheria toxoid has already been approved for use as a carrier for human vaccines (see page 14, fist paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Russell-Jones et al. teach the claimed method except for use of immunodominant foreign T cell epitopes derived from diphtheria toxoid, Russell-Jones et al. teach that immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art and that diphtheria toxoid was already approved as a carrier for human vaccines. One of ordinary skill in the art would have been motivated to do so because immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art and diphtheria toxoid was already approved as a carrier for human vaccines.

Regarding applicants comments about "self proteins", Russell-Jones et al. teaches that the claimed invention can be used as a vaccine in humans (see page 33) and can be used to raise antibody responses against such proteins as luteinizing hormone, somatostatin, inhibin, FSH (eg. ***self proteins***). Russell-Jones et al. teach that, "The at least one "immunogen" which forms part of the complex *is any molecule which it is desirable to use to raise an immune response*.". Regarding applicants comments about somatostatin, there is no evidence of record that the invention of Russell-Jones et al. lacks enablement regarding this particular embodiment. The prior art is considered enabled in the absence of evidence to the contrary. Regarding applicants comments, Russell-Jones et al. teach that their invention encompasses vaccines for use in animals and humans (see page 33). Russell-Jones et al. teach that one such immunogen could include luteinizing hormone or somatostatin or FSH or inhibin (see page 9). Said proteins could only be of two different origins (human or nonhuman). Thus, based on the disclosure of Russell-Jones et al., one of ordinary skill in the art would at once envisage use of human self-protein as a vaccine as per page

33 of Russell-Jones. Russell-Jones et al. teach Trat T cell epitopes are inserted into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26, page 31, lines 4-8, claim 14 and Abstract). Russell-Jones et al. teach that the Trat peptide is inserted such that the protein still functions as an immunogen. Russell-Jones et al. teach that the Trat modified immunogen can be used as a vaccine in a composition containing an adjuvant such as saponin (see page 8 and 13). Russell-Jones et al. teach that using recombinant DNA technology that Trat peptide can be inserted into the immunogen via substituting Trat peptide for a peptide contained in said molecule (see page 31, first incomplete paragraph and claim 14 wherein the nucleic acid of claim 14 is used to recombinantly produce said protein). Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Russell-Jones et al. teach that such vaccines can be used in animals and humans.

One of ordinary skill in the art would have been motivated to combine the aforementioned teachings because immunodominant foreign T cell epitopes derived from diphtheria toxoid were known in the art and diphtheria toxoid was already approved as a carrier for human vaccines. Furthermore, in the post KSR Int'l Co. v. Teleflex Inc. universe, motivation per se is not even required in a rejection under 35 USC 103. In KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007)

it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

Regarding applicants comments and the Travers, Schmidt, Borregaard and Zinkernagel declarations, said declarations have been addressed in the previous Office actions or addressed above. Regarding applicants comments about paragraph 10 of the Travers declaration, Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Regarding applicants comments about “suppressor

regions", that particular example of the Russell-Jones et al. reference is not referred to in the instant rejection.

12. Claim 101 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russell-Jones et al. in view of Dean et al. (US Patent 5,716,596) as applied to claims 85-87 above, and further in view of Hellman (WO 93/05810) and Le et al. (US Patent 5,698,195).

The previous rejection renders obvious the claimed invention except for use of TNFα. Hellman teaches that modulation of self proteins responsible for manifestations of a particular disease can be achieved using self-protein conjugated to a carrier which is recognized by T helper cells(see pages 5-12) and wherein the administered hybrid molecule elicits antibodies against said molecule. Le et al. teach that antibodies against TNFα are used to treat TNFα mediated diseases in humans (see abstract and column 5). It would have been prima facies obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the use of anti TNFα antibodies to treat TNFα mediated disease was known in the art, Hellman teaches that modulation of self proteins responsible for manifestations of a particular disease can be achieved by inducing antibodies against said molecules using self molecules that contain T helper epitopes and Russell-Jones et al. teach methods for inducing antibodies against self proteins using Trat modified molecules.

Applicants arguments are as per addressed above.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron, Ph.D./
Primary Examiner, Art Unit 1644